IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' RENEWED *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI

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INTRODUCTION

Plaintiffs' opposition ("Opp.") ignores and is at odds with Mr. Rafalski's own sworn trial testimony. It also mischaracterizes Mr. Rafalski's methodologies, Defendants' arguments, and the governing case law. It therefore provides no meaningful answer to the grounds for exclusion set out in Defendants' renewed *Daubert* motion.

The disconnect between Plaintiffs' arguments and Mr. Rafalski's actual testimony is best highlighted by Plaintiffs' assertion that Mr. Rafalski's flagging methodologies will assist the Court in "identify[ing] the suspicious orders that Defendants failed to identify, investigate or block." Opp. 3. Contrary to Plaintiffs' suggestion, Mr. Rafalski expressly disavowed any opinion that the orders identified by his flagging methodologies were "suspicious orders" within the meaning of the governing regulations:

> Q. … Do you know how many of these tens of millions of [flagged] orders should have been reported to the DEA as suspicious?
>
> A. No, I do not.

5/26 Tr. at 229:24–230:2. Because it is undisputed that Defendants have no general obligation to block an order that does not meet the regulatory definition of "suspicious," Mr. Rafalski's testimony makes clear that his flagging methodologies cannot possibly assist the Court in identifying "suspicious" orders that Defendants should have reported and/or blocked. His testimony makes equally clear that he cannot even advance a methodologically coherent position as to the basic purpose of his flagging exercises.

Plaintiffs' refrain in response to all of Defendants' arguments is that the MDL court denied Defendants' pre-trial motion to exclude Mr. Rafalski. *See, e.g.*, Opp. 2, 6–7, 10, 11–12, 14, 15,

17, 21.[1] But this Court, too, determined that the better course would be to deny Defendants' pre-trial motion, hear Mr. Rafalski's testimony, and ***then*** decide whether it satisfies the requirements for expert testimony under *Daubert*. Because Mr. Rafalski has now completed his testimony, the time is passed for lawyer arguments about how Mr. Rafalski's opinions might or might not be supported. The question before this Court is whether Mr. Rafalski's actual trial testimony establishes that he employed sufficiently reliable methodologies in reaching his opinions that those opinions should be admitted. As Plaintiffs' counsel candidly acknowledged, ***that*** is not a question that Judge Polster (or any other court) has answered.[2] And the answer to that question is clear: he did not.

ARGUMENT

I. PLAINTIFFS FAIL TO RESUSCITATE MR. RAFALSKI'S UNRELIABLE FLAGGING METHODOLOGIES.

Plaintiffs' assertion that Defendants failed to identify "any actual flaw" in Mr. Rafalski's methodologies and instead "aim[ed] their fire at his conclusions" is demonstrably incorrect. Opp. 1. Defendants' criticisms are aimed squarely at Mr. Rafalski's flawed and, in some cases, nonexistent methodologies. Moreover, the fact his methodologies produce such an implausible result reinforces the flaws of his methods, including when it is so evident that he has no methodology for reconciling his 90% figure with facts he readily conceded, such as that almost all prescribing is legitimate. 5/26 Tr. at 120:14–19. Because Plaintiffs offer no meaningful answer

[1] Notably, the MDL court failed to consider the four factors for assessing expert reliability set forth by the Supreme Court in *Dabuert*. *See generally*, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934490, at *1 (N.D. Ohio Aug. 20, 2019). For that additional reason, the MDL court's decision is neither controlling nor persuasive as applied here.

[2] *See* 5/27 Tr. 57 ("What we've been doing is maybe a pre-fight with the *Daubert* motions in CT1 and in New York. But this is the first time there's been a trial on the distributors and an expert witness in the country.").

to those methodological challenges—and because their own arguments are squarely contradicted in several instances by Mr. Rafalski's actual testimony—they fail to show that the testimony should not be excluded.

A. Methods A and B Should Be Excluded.

Not Based on *Masters*. Plaintiffs assert that Methods A and B are reliable because they were "endorsed by the court of appeals in *Masters*," Opp. 8, but that assertion is untrue and belied by Mr. Rafalski's own testimony.

Mr. Rafalski admitted that neither Method A nor Method B is actually based on the system used by Masters Pharmaceuticals and discussed by the D.C. Circuit in its 2017 opinion. *See, e.g.*, 5/26 Tr. at 235:10-16 & Ex. 1[3] (admitting that Method A "was not used in the Masters program in the real world"), 5/26 Tr. at 238:13–21 (claiming that Method B was "similar" to the Masters program but admitting that there were "difference[s]"). Mr. Rafalski further admitted that his Methods were in fact nothing more than "stylized illustrations," 5/26 Tr. at 222:1–4, that do not "precisely implement ***any*** Suspicious Order Monitoring System used in the real world," 5/26 Tr. at 220:14–19 (emphasis added). Accordingly, Plaintiffs' attempt to justify Methods A and B by reference to the system used by Masters and discussed in the *Masters* decision founders on Mr. Rafalski's own sworn testimony.[4]

[3] Exhibit 1 is the transcript of the video deposition testimony that was played in open Court at 5/26 Tr., 235:12.

[4] Plaintiffs are also wrong to assert that the D.C. Circuit "endorsed" the system used by *Masters*. Rather, the court merely evaluated whether Masters had complied with 21 C.F.R. § 1301.74(b). *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212 (D.C. Cir. 2017) (noting "[t]his case challenges DEA's 2014 decision to revoke Masters' certificate of registration and that "[t]he revocation order turned on DEA's conclusion that Masters had shirked its legal obligation to report suspicious orders for controlled substances").

No-Diligence Assumption Unfounded. Plaintiffs are wrong in suggesting that Defendants' challenge to Mr. Rafalski's assumption that no due diligence was done goes merely to the weight of the evidence. *See* Opp. 10–12, 15. Mr. Rafalski's own testimony makes perfectly clear that he ***assumed*** no due diligence was done as part and parcel of his ***methodology***. He admitted that he did not review "***any*** of the orders flagged by [his] methodologies," including any of the "initial triggers," before making his no-due-diligence assumption, 5/26 Tr. at 214:13–215:6:

> Q…. Have you looked at those initial orders for McKesson, Cardinal and ABDC that are the initial flagged orders of your Method A?
>
> A. I have not, Your Honor.
>
> Q. Did you individually review any of them to see if you just looked at the order on its face whether you would consider it to be suspicious?
>
> A. I did not, Your Honor.

5/26 Tr. at 227:20–228:3. Nor did he review the "diligence files" for each of the "flagged orders" or "look[] at which pharmacies generate the most flagged orders" before employing his assumption. 5/26 Tr. at 215:8–10, 228:4–11. Rather, he merely "assum[ed]" that no diligence was done. *See, e.g.*, 5/26 Tr. at 227:1–9. This was an essential element of his methodology.

Plaintiffs attempt to back-fill this opinion by pointing to Mr. Rafalski's subsequent partial reviews of Defendants' document productions, Opp. 10–11, but again Mr. Rafalski's own testimony gets in their way. As described above, Mr. Rafalski admitted that he did not review all of the diligence files or any of the flagged orders. While Plaintiffs attempt to justify the assumption by asserting that the "absence of documentation means an absence of due diligence," Opp. 11, they are once again contradicted by Mr. Rafalski's own sworn testimony. Mr. Rafalski admitted that the absence of more complete diligence files in Defendants' records was ***not*** necessarily an

indication that proper diligence was not done at the time orders were placed. Specifically, he admitted that

- he does not know, of his flagged orders, how many were "actually investigated and the flag cleared by the defendants," 5/26 Tr. at 228:21–229:6;
- no regulation requires wholesale distributors to retain diligence files—many of which would be decades old, 5/26 Tr. at 269:21–25; and
- older documents may not have been produced in this litigation merely because they "weren't kept" by Defendants up through the time that litigation commenced, 5/27 Tr. at 12:23–13:6.

Accordingly, Mr. Rafalski simply does not have the knowledge—and has not done the work—that would be needed to justify his no-diligence assumption.[5]

This is especially clear in light of the fact that Mr. Rafalski's assumption is contradicted by the undisputed factual record that Plaintiffs themselves have developed in their case. As described in Defendants' opening brief, representatives of each Defendant testified at length about the substantial amounts of diligence that Defendants did before increasing thresholds or shipping orders that were flagged by their SOM systems. *See* Br. 6–7. While Plaintiffs assert that experts may rely on assumptions or facts that are not in the record, *e.g.*, Opp. 5, the case law makes clear that an expert opinion based on facts that are contrary to the record is not helpful to the trier of fact and is inadmissible.[6] *See Tyger Const. Co. Inc. v. Pensacola Const. Co.*, 29 F.3d 137, 142–143

[5] Plaintiffs' argument that *Masters* supports the inference from an absence of diligence files to an absence of diligence is misplaced. Opp. 12. While the absence of a *contemporaneous* business record may be some evidence that a transaction did not take place, the absence of more complete files *decades after* the events in question took place would not—especially where, as here, there was no obligation to retain those records, *see* 5/26 Tr. at 269:21–270:14, and the undisputed fact testimony reflects that diligence was done.

[6] The case law also makes clear that expert opinions that fail to take account of and explain contrary evidence are unreliable. *See, e.g.*, *Trana Discovery, Inc. v. S. Rsch. Inst.*, 915 F.3d 249, 255 (4th Cir. 2019) (concluding that "[a]n expert must offer an opinion that fits the case at hand" and methodologies "that simply ignore[] key evidence veer[] into speculation"); *United States v.*

(4th Cir. 1994) (stating that "[a]n expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record" and excluding putative expert whose calculation "was based on a faulty assumption that is unsupported by the evidence"); *see also Perry v. Scruggs*, 17 Fed. Appx. 81, 87 (4th Cir. 2001) (excluding expert because his "assumptions are speculative and not supported by the record"); *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (excluding expert opinion that was based on assumption that "had no apparent support in the record").

Finally, while Plaintiffs point to the allegedly "low number of suspicious order reports actually made by Defendants" as supposed evidence of inadequate diligence, Opp. 11, that argument has three fatal flaws. *First*, Mr. Rafalski admitted that his methodologies do not actually flag orders that should have been reported by Defendants to DEA:

> Q…. Do you know how many of these tens of millions of [flagged] orders should have been reported to the DEA as suspicious?
>
> A. No, I do not.

5/26 Tr. at 229:24–230:2. Because the orders "flagged" by Mr. Rafalski avowedly do not represent orders that Defendants should have reported to DEA, it makes no sense to point to the divergence between flagged orders and reported orders as evidence of anything. *Second*, Plaintiffs' argument entirely ignores the reason that orders were increasing. If, as the undisputed record evidence shows, doctors were in good faith prescribing an increasing amount of opioid medications during the relevant time-period, *see* Br. 12, 23 & n.18, then there would not have been anything "suspicious" about the increase in orders. *Third*, Plaintiffs' argument assumes what Mr. Rafalski is supposedly trying to prove: the absence of more DEA reporting could be evidence of insufficient

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Walton, 86 F.3d 1154 (4th Cir. 1996) (holding that "opinion of the expert must fit the facts" and affirming exclusion of expert testimony that was contrary to record evidence).

due diligence only if there were in fact a large number of additional orders that should have been reported.

"Subsequent Order" Opinion Unfounded. Plaintiffs' attempt to justify Mr. Rafalski's methodology of flagging all orders subsequent to an initially flagged order is likewise wholly unavailing.[7]

While Plaintiffs purport to justify this methodology by reference to *Masters*, *see* Opp. 8, Mr. Rafalsi admitted that his no-diligence assumption "was not used in the Masters program in the real world." 5/26 Tr. at 235:10–16 & Ex. 1.[8] He further admitted that it "wouldn't be a valid exercise for the DEA" to "apply the assumption" to identify diversion. 5/26 Tr. at 236:16–23. And, most damning of all for purposes of *Daubert* scrutiny, he admitted that he could not identify any "general acceptance" for the assumption, whether by "distributors, regulators or academics" and that it has never been used by anyone except him in this litigation. *See* 5/26 Tr. at 223:18–21, 236:12–15. Accordingly, the Court should not permit Mr. Rafalski to offer opinions based on this not-used-in-the-real-world, created-for-litigation methodology. *See* 5/26 Tr. at 220:14–19, 222:5–13, 223:18–21.[9]

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[7] While Plaintiffs' brief refers to Mr. Rafalski's assumption that all subsequent orders should be flagged and blocked as the "subsequent order" assumption, Mr. Rafalski himself referred to it in his testimony as part of his no-diligence assumption.

[8] Dr. McCann, who actually created the code generating the analyses relied on by Mr. Rafalski, likewise admitted that Method A was *not* part of the Masters suspicious order monitoring program. *See* Ex. 1 (McCann Dep. Tr.) at 115:16–23 (agreeing that Method A "does not follow … the operating procedures for the SOMS program described in the Masters Pharmaceutical Comprehensive Compliance Policy Manual"), 119:1–7 (same).

[9] Plaintiffs argument that the assumption is supported by the DEA's administrative action in *Southwood* is also incorrect. In *Southwood*, the registrant supplied controlled substances to internet pharmacies "under … suspicious circumstances." *Southwood Pharmaceuticals, Inc.*; Revocation of Registration, 72 Fed. Reg. 36,487, 36,487 (July 3, 2007). DEA's statement that the result of repeatedly shipping facially such facially problematic orders was "likely diversion" provides no support for application of Mr. Rafalski's assumption flagging all subsequent orders.

Plaintiffs' attempt to justify the assumption by reference to the actual operation of Defendants' SOM programs is also misplaced. As Defendants explained in their opening brief, since at least 2008 ***each Defendant has operated a system that identifies and does not ship suspicious orders***. *See* Br. 14. Plaintiffs tellingly failed to dispute that ***Mr. Rafalski never testified that the thresholds used by those systems to flag suspicious orders were set too high*** or were otherwise inadequate. Instead, Mr. Rafalski merely opines that Defendants could instead have used one of his (highly flawed) methodologies.

Of course, it is unsurprising that—had Defendants used different criteria (such as Mr. Rafalski's) to identify suspicious orders—their systems would have flagged different subsets of orders. But it makes no sense to criticize Defendants for not conducting additional diligence on orders that were not flagged by the systems that Defendants actually use, merely because they would have been flagged if they had instead used one of Mr. Rafalski's methodologies. Yet that is precisely what Mr. Rafalski does: he applies his methodologies, flags certain orders, and then assumes that all subsequent orders were somehow suspicious, should have been blocked, and (because they were not blocked) were likely to be diverted. Put differently, Defendants each designed systems (again, using thresholds that Mr. Rafalski did not criticize) that flagged certain orders and, when orders were flagged, appropriately responded to the "alarm bell." Accordingly, the suggestion that over 90% of Defendants' orders should have been blocked merely because Defendants did not investigate Mr. Rafalski's counter-factual "alarm bells" has no basis in any sound methodology.

Ignores the Real-World. Plaintiffs attempt to counter Defendants' criticism about the implausibility of Mr. Rafalski's 90% opinion as a purportedly impermissible attack on his conclusions, but Defendants' criticisms in fact go directly to the unreliability of his methodology.

For example, Mr. Rafalski acknowledged that, during the relevant time period, "doctors in Huntington and Cabell County were making the decision to prescribe more and more," 5/26 Tr. at 242:6–11, yet he did not take that (or the corresponding increase in DEA quotas) into account when developing his flagging methodologies:

> Q…. Method B does not adjust threshold levels at all based on whether doctors are making the judgment to legitimately prescribe more or less prescription opioids, correct?
>
> A. That's correct, Your Honor.
>
> ***
>
> Do you know how many flagged orders you would generate if you did take changes in prescribing or changes in the quota and used them to adjust your maximum?
>
> A. No, I do not.

5/26 Tr. at 242:21–243:13, 247:20–23. As a result of Mr. Rafalski's failure to consider these real-world impacts, he was left unable to say how many patients with cancer, or recovering from surgery, or dealing with end-of-life pain would have been deprived of vital medicines if Defendants had, in fact, blocked a full 90% of all orders for opioid medicines they received from pharmacies in Huntington/Cabell. 5/26 Tr. at 217:2–218:14. Accordingly, the 90% figure is compelling evidence that Mr. Rafalski's ***methodologies***—which entirely ignore what was happening in the real world—are unreliable.[10] *See generally Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) ("As the Supreme Court has recognized, 'conclusions and methodology are not entirely distinct from one another.'" (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997))); *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3rd Cir. 1999) ("While

[10] Plaintiffs offer no response to the methodological critique that Mr. Rafalski has no basis for treating hospital pharmacies differently from other pharmacies, which is a concession of this flaw. *See* Br. 25.

'[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate, a district court must examine the expert's conclusions in order to determine whether they could reliably follow from the facts known to the expert and the methodology used." (citation omitted)).

Fails *Daubert* Tests. Finally, Plaintiffs offer no meaningful response to Defendants' showing that Mr. Rafalski's opinions fail each of the four basic factors set out in the Supreme Court's *Daubert* opinion. While Plaintiffs observe that these factors are "non-exhaustive," they do not point to a single case holding that an expert's opinion is admissible where it flunks ***all four*** factors. *See* Opp. 4, 22.

Testing and Peer Review. Defendants' opening brief conclusively established that Mr. Rafalski's opinions are not used by the DEA, have not been peer reviewed or tested, and are not based on academic or other work that has been peer reviewed or tested. *See* Br. 27–28. Plaintiffs' opposition makes no effort to rebut that showing. Accordingly, it is undisputed that Mr. Rafalski's opinion fails the first two *Daubert* factors.

General Acceptance. Plaintiffs contradict Mr. Rafalski's sworn testimony when they argue that his methodologies have "general acceptance." Opp. 22. For example, Mr. Rafalski testified:

> Q. There's no general acceptance you can point me to for Method A with its due diligence assumption, whether it's by distributors, regulators or academics, correct?
>
> A. That is a correct statement, Your Honor.
>
> ***
>
> Q. And you can't point me to any generally accepted methodology for identify and reporting suspicious orders that ignores entirely what the medical community is doing in terms of increased legitimate prescriptions, true?
>
> A. That's a correct statement.

5/26 Tr. at 236:12–15, 242:1–5. Plaintiffs further contradict Mr. Rafalski when they argue that Methods A and B have general acceptance because they have been used by "the DEA and endorsed by a federal appeals court." As explained above, Mr. Rafalski's testimony made clear that his methodologies were not the same as those discussed in *Masters*. Accordingly, Mr. Rafalski admittedly fails the general acceptance factor.

Error Rate. Plaintiffs do not contest that there is a 400% rate of error in the number of orders flagged by Methods A and B. Instead, they argue that "no greater precision is required" because "Methods A and B are not a single technique." Opp. 3, 16. That argument misses the mark. Mr. Rafalski affirmatively represented to the Court that both Method A and Method B could reliably be used to identify "suspicious" orders of controlled substances. The fact that those two methodologies generate a ***400% difference*** in flagged orders demonstrates that both cannot possibly be reliable. Imagine, for instance, that a putative psychiatry expert endorsed two set of criteria for diagnosing PTSD in a group of veterans, one of which purported to show that 90% had PTSD while the other purported to show that 20% did. Under those circumstances, a court would not likely credit the expert for offering the court a "range of [options]" for diagnosing PTSD, as Plaintiffs suggest, Opp. 1. Rather, the court would throw both out because they could not possibly both be correct. The same conclusion is warranted here: a 400% error rate demonstrates that Methods A and B could not both possibly be reliable. *See, e.g.*, *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 18, 25 (D. Mass. 1995) (finding an expert's estimate with a 25-30% error rate unreliable); *Gazzara v. Pulte Home Corp.*, 2017 WL 840953, at *8 (M.D. Fla. Mar. 3, 2017) (excluding an expert whose theory had an error rate of roughly 50 percent).

B. Methods C Through F Should Be Excluded.

Perhaps nowhere is the disconnect between what Plaintiffs say in their brief and what Mr. Rafalski said in his sworn testimony greater than in Plaintiffs' attempt to resuscitate four

methodologies that Mr. Rafalski unambiguously disavowed on cross-examination. Plaintiffs' continued reliance on methodologies that their own expert specifically disavowed demonstrates that Mr. Rafalski's testimony cannot be admitted under *Daubert*.

Mr. Rafalski could not have been clearer when he testified that "if someone was to come to me and say should I use these methodologies, … ***I would tell them no***," and that, "[i]f I owned a company, a distributor, and I was going to design a suspicious order system, … ***I would not use*** [***Methods C–F***]." 5/26 Tr. at 224:25–225:12. Plaintiffs' brazen attempt to minimize this testimony as merely the "personal preference" of Mr. Rafalski entirely misses the point. Opp. 20. If Mr. Rafalski, as Plaintiffs' putative expert, would not recommend using these methodologies because (in language Plaintiffs ignore) they admittedly "would not be effective," 5/27 Tr. at 10:5–7, then by his own concessions they are not reliable methodologies.

Plaintiffs' attempt to rescue these methodologies by claiming that Methods C through F have been used by Defendants again flies in the face of Mr. Rafalski's own testimony. Mr. Rafalski admitted that all of his methodologies are merely "stylized illustrations" that he created for litigation and that "none… precisely implement[s] any Suspicious Order Monitoring System used in the real world." 5/26 Tr. at 220:14–19, 222:1–4. An examination of the three methodologies that supposedly represent approaches used by Defendants confirm that Plaintiffs are wrong:

- **Method D**. Plaintiffs cite testimony from AmerisourceBergen's Chris Zimmerman and Cardinal Health's Michael Mone to claim that the "companies' representatives" acknowledged use of Method D's "the three times-monthly average approach." Opp. 18. But Mr. Zimmerman testified that there was flexibility in the multiplier ABDC used and that the multiplier was a function of instructions from DEA.[11] And Mr. Mone testified that

[11] 5/13 Tr. at 55:4–17 ("A]fter two years using different multipliers, [ABDC] settled at three, but that was completely flexible. Each [DEA] office could have it at zero. They could have it at six. We had some [offices] that wanted it higher, six. Some wanted zero. It was completely up to the DEA office what multiplier they wanted."); *see also id.* at 55:18–28 ("Q. So, if the four-month average was ten, how many pills could a pharmacy order before your system would flag it the next

Cardinal Health applied a multiplier of three only after first dividing customers into segments (e.g., hospital, retail pharmacy, etc.) and then subcategorizing by size (e.g., small, medium, and large). 5/26 Tr. 59:5–61:2. Thus, unlike Rafalski's Method D, Cardinal Health initially set segment- and size-specific thresholds, not a universal threshold based on "the national average" or a "West Virginia transaction average."

- **Method E**. Plaintiffs assert that Method E is "based on a policy that was used by Defendant McKesson Corporation beginning in or about May 2007." Opp. 18–19. In attempting to tie Method E to McKesson, Plaintiffs understandably do not rely on Mr. Rafalski because he (1) did not testify that it was based on McKesson's SOM program, *see* 5/26 Tr. at 93:22–94:19, and (2) conceded on cross-examination that the static "8,000 dosage unit" methodology set forth in Method E ***was not actually used by McKesson or anyone else*** to block suspicious orders, *see* 5/27 Tr. at 10:8–11:5. While Plaintiffs rely on the testimony of McKesson's Michael Oriente, he testified that the 8,000 dosage unit limit existed only under the LDMP program that was in place only briefly, from June 2007 to May 2008, and (as Mr. Rafalski himself confirmed) was ***never*** used as a static order threshold. *See* 5/24 Tr. at 31:23–32:3.

- **Method F**. Plaintiffs assert that Method F is "based on a policy put in place by Defendant Cardinal Health from the early 1990s until at least 2008," Opp. 19, but Mr. Rafalski did not testify to that, 5/26 Tr. 94:20–95:21. In any event, the Cardinal Health compliance manual cited by Plaintiffs, Opp. 19 (citing P-09320), makes clear that the charts did not set a threshold over which orders are presumed suspicious and instead were intended only to "assist" personnel. P-09320_00046.; *see also* Reardon Designated Dep. Tr. 512:10–513:4 (testimony by former head of Cardinal Health's anti-diversion program).

For all these reasons, the Court should exclude Mr. Rafalski's four abandoned methodologies.

Moreover, Plaintiffs' continued reliance on six disparate methodologies calls the entirety of Mr. Rafalski's opinions into question. The spread between Mr. Rafalski's diversion estimates across his six methodologies is from 20.2% to 99.8% depending on Defendant and medication. *See* 5/26 Tr. at 96:10–101:21. As explained above, an expert who offers the court so wide a range is not providing helpful testimony; he is effectively demonstrating that all of his different methodologies could not possibly be correct. *See supra* p.11.

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month? A. It depends on what the DEA office wanted. If they wanted the three multiplier, it would be 30. If they wanted the zero multiplier, it would be ten.").

II. PLAINTIFFS FAIL TO RESUSCITATE MR. RAFALSKI'S UNSUPPORTED *IPSE DIXIT* OPINIONS.

At the tail end of his direct testimony, and without any explanation of the bases for his opinions or the methodologies supporting them, Mr. Rafalski offered three *ipse dixit* opinions that were not grounded in any reliable methodology identified in the course of his prior testimony: (1) the orders identified by his flagging methodologies were "more likely than not" diverted, (2) Defendants' SOM programs were insufficient, and (3) the alleged insufficiencies in Defendants' programs were a "substantial factor" in diversion in Huntington/Cabell. The Opposition itself demonstrates precisely why these *ipse dixit* diversion opinions should be excluded.

Tellingly, Plaintiffs do not even attempt to articulate any methodology used by or point to any evidence cited by Mr. Rafalski in offering these opinions—because there was none. Instead, they simply (1) detail Mr. Rafalski's experience as a DEA diversion investigator and (2) restate his conclusions with no more explanation or elaboration than offered by Mr. Rafalski himself. But his "background and experience as a DEA Diversion Investigator," Opp. 23, is not a methodology to determine whether Mr. Rafalski employed a reliable methodology in determining that Defendants' SOM programs were deficient and that the orders flagged by his methodologies were likely diverted in Huntington/Cabell. No matter how allegedly well-qualified an expert might be, it is well-established that the expert must separately articulate and employ a reliable methodology in offering his opinions. *See, e.g.*, *Nease v. Ford Motor Co.*, 848 F.3d 219, 232 (4th Cir. 2017) (holding that an expert who "did not employ a particular methodology to reach his conclusions" should have been excluded); *Cooper*, 259 F.3d at 200 (noting that "[a] reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation," and excluding putative expert who "asserted what amounted to a wholly conclusory finding based

upon his subjective beliefs rather than any valid scientific method").[12] That is what Mr. Rafalski failed to do.

Under Rule 702, "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts"; the "trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 advisory committee's note (2000 amend.) Yet that is what Plaintiffs are asking the Court to do here—take Mr. Rafalski's word for it. In essence, they argue that the Court should credit Mr. Rafalski's *ipse dixit* opinions because he (1) has experience as a DEA diversion investigator and (2) reviewed some (but by no means all) of Defendants' policies, procedures and other documents. *See* Opp. 23. But at no point did Mr. Rafalski ever explain to the Court the criteria or facts used in reaching his bottom-line conclusions—leaving the Court with no ability independently to evaluate the strengths and weaknesses of his conclusions. That is precisely what the rules prohibit. *See, e.g.*, *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999) ("[Q]ualifications alone do not suffice. A supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under the test set forth by the Supreme Court in *Daubert*.").

[12] *See also, e.g.*, *United States v. Frazier*, 387 F.3d 1244, 1261 (11th Cir. 2004) ("Of course, the unremarkable observation that an expert may be qualified by experience does not mean that experience, standing alone, is a sufficient foundation rendering reliable any conceivable opinion the expert may express. … [O]ur caselaw plainly establishes that one may be considered an expert but still offer unreliable testimony."); *Bourelle v. Crown Equipment Corp.*, 220 F.3d 532, 537 n.11 (7th Cir. 2000) (noting that the court treats reliability separate from the expert's qualifications, and affirming the exclusion of a qualified expert whose opinions were unreliable).

Here, moreover, Plaintiffs entirely ignore the myriad of very good reasons offered in Defendants' brief for ***not*** taking Mr. Rafalski's word for it. For instance, Mr. Rafalski admitted that, when forming his *ipse dixit* opinions, he

- did not know "how many" of the "suspicious orders that have occurred over time" were "actually diverted," 5/26 Tr. at 205:18–22;
- did not "actually review any of the orders" that he concluded "were likely to be diverted" before rendering his opinions, 5/26 Tr. at 214:13–15, 215:1–7;
- did not assess the medical need for prescription opioid medications in Cabell County and does not "know how many of those orders went to fill legitimate medical need," 5/26. Tr. at 129:4–7, 216:13–18, 216:23–217:1, 218:15–20;
- did not identify "a single doctor … in Cabell County or Huntington who was prescribing improperly or engaging in diversion," 5/26 Tr. at 128:11–15;
- was not "aware of any pills that were shipped by [Defendants] that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription," 5/26 Tr. at 131:6–10;
- was not aware of any actual diversion occurring in Cabell/Huntington at the "pharmacy level," 5/26 Tr. at 135:8–13;
- did not know what percentage of the orders he identified as likely to be diverted "were actually investigated and … cleared" by Defendants, 5/26 Tr. at 228:21–6;
- did not know how many of those orders were suspicious on their face or "should have been reported to the DEA as suspicious," 5/26 Tr. at 227:25–228:3, 229:24–230:2;
- did not consider that DEA estimated "less than .1 percent diversion" for oxycodone and hydrocodone, 5/26 Tr. at 249:11–250:13; and
- while acknowledging that "legitimate" prescribing of opioids increased significantly during the relevant time period, 5/26 Tr. at 242:6–11, 244:7–13, failed to consider any of the real-world changes that affect distribution levels, *see id.* at 241:8–12, including shifts in medical need, increases in the DEA quota, population shifts, or other demographic changes, *id.* at 241:17–25, 245:9–12.

Defendants detailed each of these failings in their opening brief, and Plaintiffs offered no response to any of them. A methodology that ignores all of these critically relevant facts—as Mr. Rafalski admittedly did—could not possibly be reliable.

Plaintiffs attempt to rescue Mr. Rafalski's opinions by reference to legislative and other public sources materials—many of which Mr. Rafalski did not himself rely on—recognizing that downstream diversion ***may*** occur if a DEA registrant fails to maintain effective controls. Opp. 23–24. But that is beside the point.[13] Rather, the questions here are whether Defendants' SOM programs were deficient and whether those alleged deficiencies "more likely than not" led to diversion in Huntington/Cabell. The scattershot materials underlying Plaintiffs' lawyer argument (but not Mr. Rafalski's testimony) do not even arguably speak to those questions.

Finally, Mr. Rafalski's (and Plaintiffs') continued inability to articulate precisely what his methodologies are supposed to represent further demonstrates the unreliability of his *ipse dixit* opinions. On the one hand, when it suited him, Mr. Rafalski makes the strong claim that each of the "tens of millions of orders" flagged by his methodologies "were likely to diverted." 5/26 Tr. at 214:10–12. Yet, on the other hand, he quickly retreated from that position when pressed. *See, e.g.*, 5/26 Tr. at 217:2–20 (flagged orders represent "pills [that] ***could*** have the ***potential*** for diversion").[14] Most notably, Mr. Rafalski expressly disavowed even the assertion that his flagged orders were "suspicious orders" that should be reported to DEA pursuant to 21 C.F.R. § 1301.74(b). *See* 5/26 Tr. at 229:24–230:2. And, as Defendants have explained, there is no basis for the assertion that an order that was not even reportable to DEA should have been blocked or was "more likely than not" diverted. Plaintiffs have no answer to this argument.

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[13] For instance, Defendants do not take issue with the proposition that "where suspicious orders are placed '*over extend periods of time*, [this] would lead a reasonable person to believe that controlled substances *possibly* are being diverted.'" Opp. 24 (citing P-09307 (DEA Diversion Manual) at bates page 01176301)) (emphasis added) (alteration in original). But that assertion does nothing to show that Defendants' conduct "more likely than not" led to actual diversion in Huntington/Cabell.

[14] Compare 5/26 Tr. at 217:2–5 (asserting that "90 percent of the pills should not have been shipped"), *with id.* at 217:15–17. ("not saying that none of those 90 percent would actually have been distributed").

In short, Mr. Rafalski's work as a former DEA employee is not enough. To be admissible, his opinions must also be supported by a reliable methodology. Because his three *ipse dixit* opinions were not supported by any methodology, those opinions should be excluded as unreliable.

CONCLUSION

The Court should exclude Mr. Rafalski's unreliable opinions pursuant to Rule 702.

Dated: June 4, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 4th day of June, 2021, the foregoing "REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' RENEWED *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI" was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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